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By _____
(Signature of person mailing)
Patricia Botelho
(Typed or printed name of person)

PC10755AJTJ 14/Election

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT:
William J. Curatolo, et al.

:Examiner: B. Fubara

SERIAL NO.: 09/742,785 :Art Unit: 1615

FILED: December 20, 2000 :

Bet 9-5-03

FOR: Pharmaceutical Compositions
Providing Enhanced Drug Concentrations

Commissioner for Patents
PO Box 1450
Alexandria, VA 22131-1450

Sir:

RESPONSE TO REQUIREMENT FOR ELECTION

This is in response to the Office Action, an election (of species) requirement, mailed on April 11, 2003, the term for response having been extended three (3) months by including the appropriate fee and petition herewith.

In response to the Office Action, applicants elect the species wherein the solubility-improved form of the drug is a crystalline highly soluble salt form (for example, see claim 2), and wherein the polymer is an ionizable cellulosic polymer (for example, see claim 16). Claims 1-2, 12-18, 25-31, 41-47, 54-59, 69-75, 82-87, 92-95, 102-107, 112-115, 122-127, 132-135, 142-147, and 151-155 are readable on the elected species.

Applicants note the observations made by the Examiner in Paragraph 4 on page 4 of the Office Action. Applicants comment as follows:

In regard to the missing US patent number at page 3, line 20 of Applicants' specification, no US patent has yet issued. The US patent number corresponding to the PCT application indicated will be inserted when a US patent issues.

The Examiner commented that

> There appears not to be a description in the specification for crystalline highly soluble salt drug, high-energy crystalline drug, a concentration-enhancing polymer that has a hydrophobic portion and a hydrophilic portion. [Page 4 of the Office Action, third full paragraph]

Applicants respectfully disagree with the above comments. Applicants' specification provides a detailed description and disclosure of crystalline highly soluble salt forms of drugs and of high-energy crystalline forms of drugs. Attention is directed, for example, to the disclosure extending from Page 30, line 23 over to page 33, line 31. The terms themselves are fully explained and examples of both types of drug forms are provided. As for concentration-enhancing polymers having hydrophilic and hydrophobic portions, such polymers are termed "amphiphilic", as fully explained starting at page 37, line 1; see especially the definition given at page 37, lines 8-11. A description of preparing amphiphilic cellulosic polymers is given at page 38, starting at line 4. Specific examples of amphiphilic cellulosic polymers are given starting at page 39, line 25. Examples of non-cellulosic amphiphilic polymers are given starting at page 40, line 3. Applicants have clearly and fully illustrated and exemplified the types of polymers (cellulosic and non-cellulosic, ionizable and non-ionizable, including amphiphilic polymers) useful in their invention.

Applicants have reviewed claims 146 and 155. The Examiners' comments relating to the alleged vagueness and confusion of these claims are not understood, at least in part because the Examiner has not provided any basis as to why one skilled in the art would not find the claims clear and distinct as they stand. Applicants' respectfully submit that both claims are clear and distinct to

those skilled in the art (to whom §112 is directed), particularly in light of the abundant explanation and exemplification provided in their specification.

The Examiner's comment relating to molecular dispersions being enabled but not all dispersions, as stated in the Office Action at page 4, fourth full paragraph, is noted. It is further noted that dispersions, particularly molecular dispersions wherein the dispersion is formed prior to delivery to the use environment, do not form a part of Applicants' invention. This is stated, *inter alia*, at page 11, lines 19-24. It is accordingly respectfully submitted that whether or not dispersions are enabled should not present any issues relating to the patentability of Applicants' invention as defined by the instant claims.

Action on the merits, especially a Notice of Allowance, is respectfully requested.

Respectfully submitted,

Date: August 6, 2003

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